SEP 2 0 2002

K022869

SPECIAL 510(K) - SUMMARY OF SAFETY AND EFFECTIVENESS

August 23, 2002

Submitter: I-Flow Corporation
20202 Windrow Drive
Lake Forest, CA 92630

Contact: Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation

Trade Name: Soaker Catheter

Common Name: Anesthetic Catheter

Classification Name: Anesthesia Conduction Catheter

Existing Device: Soaker Catheter (K991543 and K994374)

Device Description: The Soaker Catheter has a closed end tip with multiple holes arranged radially along the lateral surface along the infusion segment at the distal end of the device. A membrane in the inner diameter of the catheter promotes even distribution along the infusion segment. This special 510(k) proposes a slight design change that has the membrane along the outside diameter of the catheter instead of the inside diameter.

Technology Comparison: The new Soaker Catheter utilizes the exact same technology for promoting even distribution along the infusion segment.

Conclusion: The Soaker Catheter is substantially equivalent to the existing Soaker Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2002

Ms. Shane Noehre
Director, Regulatory Affairs
I-Flow Corporation
20202 Windrow Drive
Lake Forest, California 92630

Re: K022869
Trade/Device Name: Soaker Catheter
Regulation Number: 880.5725
Regulation Name: Accessories, Infusion Pump
Regulatory Class: II
Product Code: MRZ and FRN
Dated: August 23, 2002
Received: August 29, 2002

Dear Ms. Noehre:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ver/ 3 - 4/24/96

Applicant: I-Flow Corporation

510(k) Number (if known): K022869

Device Name: Soaker Catheter

Indications For Use:

1. With I-Flow Corporation's PainBuster, ON-Q and Nerve Block pain management kits; and
2. As a stand alone device to provide continuous or intermittent delivery of local anesthetics or narcotics to surgical wound sites and/or close proximity to nerves outside of the epidural space. Routes of administration may be intraoperative, percutaneous or perineural.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Patricia Cusenza

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K022869